



American Surgical Sponges

Div. of American Silk Sutures, Inc.

K962807

DEVELOPERS OF TAKA'S™, COL-R-SPONGE™, AMERICOT™, RAY-COT™ & UNIQCOT™ SPONGES

MAY - 2 1997

ATTACHMENT #1
510(K) SUMMARY
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510(k) SUMMARY
AMERICAN SURGICAL SPONGE
NEUROLOGICAL SPONGE

Submitter Information:

American Surgical Sponges, a Division of American Silk Sutures
82 Sanderson Avenue
Lynn, MA 01921

510(k) Summary Prepared By:

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Date 510(k) Summary Prepared:

July 12, 1996

Name of the Device:

Trade or Proprietary Name:	American Surgical Sponges (brand) Neurological Sponges
Common Name:	Neurosurgical paddie or sponge
Classification Name:	Cottonoid Paddie (21 CFR 882.4700)

Identification of Legally Marketed device to which the Submitter claims equivalence:

This device is substantially equivalent to a Telfa Non-Adherent neurological sponge marketed by American Surgical Sponges, a Division of American Silk Sutures under K904517.

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Description of the Subject Devices:

The device is a non-adherent, strung, x-ray detectable surgical sponge that is sterile and disposable.

Intended Use:

This device is intended to be used by trained physicians during neurosurgical procedures to protect neural tissues from drying, abrasion, or contamination and to absorb fluids.

Technological Characteristics of the Subject Device:

Performance evaluations (comparisons with the predicate) were not conducted as there are no significant technological differences between the devices.